

JUN 20 2006

**510(K) PREMARKET NOTIFICATION SUMMARY**

**Name/Address of Submitter:** Northern Implants, LLC  
10355 B Democracy Lane  
Fairfax, VA 22030

**Establishment Registration Number:** 3003845138

**Contact Person:** Greta M. Hols  
Phone: (703) 278-3953  
Fax: (703) 278-3954

**Date Summary Prepared:** April 21, 2006

**Device Classification Name:** Endosseous Implant and Accessories

**Device Classification Regulation Number:** 21 CFR 872.3640 and 21 CFR 872.3630

**Device Regulatory Status:** Class II Special Controls

**Trade Name:** Endosseous Dental Implant

**Purpose:** The purpose of this 510(k) is to include additional implants and accessories in the NSI Endosseous Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions for our system.

**Performance Standards:** FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in the NSI Implant System meet applicable voluntary standards. Northern Implant's screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV Titanium.

**Predicate Devices:** K003620 NSI Hexed and Non-Hexed Implant System  
K020617 NSI Hexed and Non-Hexed Implant System  
K033171 NSI Hexed and Non-Hexed Implant System  
K052490 NSI Hexed and Non-Hexed Implant System  
K053478 NSI Hexed and Non-Hexed Implant System  
K894595 Straumann Implant System  
K955281 Straumann Implant System  
K012757 Straumann Implant System  
K013798 Straumann Implant System  
K990342 Straumann Implant System  
K962023 Straumann Implant System

**Device Description and Intended Use:** The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

**Sterilization Methods Used:** Sterilization of these implants will be achieved using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of  $10^{-6}$ . Validation of sterilization will be done as specified by the Association for the Advancement of Medical Instrumentation (AAMI). Standards utilized include:

ISO 11137	Sterilization of Health Care Products – Requirements for validation and routine control – Radiation sterilization
ISO 11737-2	Sterilization of Medical Devices – Microbial Methods – Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13409	Sterilization of Health Care Products – Radiation Sterilization – substantiation of 25kGy as a sterilization dose for small or infrequent production batches.

**Packaging Validation:**

All Northern Implants are packaging is validated following these standards:

ASTM D 4169-04	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88-00	Standard Test Method for Seal strength of Flexible Barrier Materials
ASTM F 1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
EN 552	Sterilization of medical devise – Validation and routine control of sterilization by irradiation
EN556-1:1997	Sterilization of medical devices – Requirements for medical devices to be labeled “Sterile”
EN 868-1:1997	Packaging materials and systems for medical devices with are to be sterilized: Part 1 General requirements and test methods
EN 868-5:1999	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
EN 868-9: 2000	Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated non-woven materials of polyolefines suitable for use as packaging of medical devices which are to be terminally sterilized – Requirements and test methods.
EN 868-10:2000	Packaging materials and systems for medical devices which are to be sterilized – Part 10: Adhesive coated nonwoven material of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirement s and test methods
ISO 11607	Packaging for terminally sterilized medical devices

**Technological Characteristics:** The physical properties and designs of the additional implants and accessories in the NSI Endosseous Dental Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

**Brief Discussion of Clinical Studies:** Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

**Conclusions Drawn:** The NSI Endosseous Dental Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.



JUN 20 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Greta M. Hols  
Director of Operations  
Northern Implants, LLC  
10355 B Democracy Lane  
Fairfax, Virginia 22030

Re: K061169  
Trade/Device Name: Endosseous Dental Implant System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: DZE, NHA  
Dated: April 21, 2006  
Received: April 27, 2006

Dear Ms. Hols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

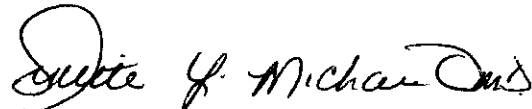
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**INDICATION FOR USE**

510(k) Number: K061169

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

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**CONCURRENCE OF CDRH OFFICE OF DEVICE EVALUATION**

Prescription Use X OR Over-the-counter Use \_\_\_\_\_

(Per 21 CFR801.109)

Susan Puoro

(Print Sign-Off)

Section of Anesthesiology, General Hospital,  
Section Control, Dental Devices

(k) Number: K061169